

**DIVISION OF HEALTH PLANNING
AND RESOURCE DEVELOPMENT
NOVEMBER 2004**

**CON REVIEW: ESRD-NIS-0904-033
RCG-MONTGOMERY COUNTY, LLC, WINONA
ESTABLISHMENT OF A SIX (6) STATION ESRD FACILITY
LOCATION: WINONA, MISSISSIPPI, MONTGOMERY COUNTY
CAPITAL EXPENDITURE: \$154,085.00**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. APPLICANT INFORMATION

Renal Care Group-Montgomery County, LLC, Winona, Mississippi (RCG of Winona) is a for-profit limited liability company that will be located in Montgomery County. The RCG of Winona is in a joint business venture with local nephrologists and Renal Care Group, Mississippi Incorporated (RCGMI), formerly known as Kidney Care. If a Certificate of Need (CON) is approved, RCGMI will be the majority owner and manager of RCG of Winona.

Kidney Care has been a provider of outpatient End Stage Renal Disease (ESRD) services in Mississippi since February 5, 1974. In 1996, Kidney Care became affiliated with Renal Care Group Incorporated (RCGI) and began operating in Mississippi under the name of Renal Care Group, Mississippi Incorporated. The Renal Care Group employs nephrologists who share the same commitments and goals as the company. Presently, RCGI operates 395 ESRD centers in 31 states (38 centers of these facilities are in Mississippi). RCGI is considered to be the largest provider of ESRD services in Mississippi.

The applicant indicates that RCG of Winona is governed by three corporate officers and is authorized by the Secretary of State to do business in the state of Mississippi. The Board of Directors consists of active nephrologists who are recognized as end-stage renal disease (ESRD) experts based on their medical training and years of experience. Since RCG has an open staff policy, nephrologists are allowed to admit and follow patients in any RCG facility. At the same time, the physician-based Board develops company policies/procedures and oversees a continuous quality improvement program (CQI Program). The program includes corporate-wide monitoring of treatment parameters such as dose of dialysis, hematocrit, albumin concentrations, hospitalization, mortality and others. Also, RCG allows licensed physicians to practice at the site.

Renal Care Group, Inc. believes that optimal care is attained through the application of state-of-the art technology, continual quality improvement and patient/family education. The RCGI responds to the changing health care environment by using networks as a tool to take on managed care responsibilities.

B. PROJECT DESCRIPTION

Renal Care Group-Montgomery County, LLC, Winona, Mississippi, requests Certificate of Need authority to establish a six station End Stage Renal Dialysis (ESRD) facility in the city of Winona, Mississippi, Montgomery County. The six station ESRD will provide accessible services to patients who travel to Renal Group facilities in Grenada, Greenwood, and Lexington but live closer to the Winona area. Also, a back-up station will be available with the six station staff-assisted hemodialysis.

The applicant states that they will enter a low-cost lease agreement with Tyler Holmes Memorial Hospital to relocate a modular building on the hospital's campus, as well as use their existing parking area to accommodate RCG of Winona ESRD patients. According to the applicant, the 1,920 square foot modular building has been designed and converted into a facility to provide dialysis treatment services. RCGMI currently leases the building from General Electric. Thus, there is no new construction associated with this project and limited site work will be completed where the modular building will be positioned. The applicant provided a non-fixed equipment list totaling \$104,085.00.

RCG of Winona states that RCGMI will transfer required staff and resources from its existing facilities to ensure services are uninterrupted so patients can continue to receive quality care. The applicant states that RCG of Winona will employ 4.35 full-time employees at an annual estimated cost of \$173,550 and contract with other businesses to provide accounting, auditing, and legal services as needed. The total proposed expenditure for this project is \$154,085.00 and operating funds will be used to finance the project. Upon the approval of the project, the completion date will take place three months after the working capital has been obligated.

II. TYPE OF REVIEW REQUESTED

The Mississippi State Department of Health reviews applications for the establishment of an end stage renal disease facility in accordance with Section 41-7-173 (h) and Section 41-7-191, subparagraph (1) (a) of the Mississippi code 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria and standards of the Mississippi State Department of Health.

In accordance with Section 41-7-197(2) of the Mississippi Code of 1972 Annotated, as amended, any affected person may request a public hearing on this project within 20 days of publication of the staff analysis. The opportunity to request a hearing expires December 6, 2004.

III. CONFORMANCE WITH THE STATE HEALTH PLAN AND OTHER ADOPTED CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The *FY 2005 State Health Plan* contains criteria and standards which the applicant is required to meet before receiving CON authority to establish a six station ESRD facility. This application is in substantial compliance with applicable criteria and standards.

SHP Criterion 1- Need

As shown in the *Fiscal Year 2005 Mississippi State Health Plan*, the Mississippi State Board of Health authorized the Department of Health to issue a CON for the construction or expansion of end stage renal facilities having a need in the following Mississippi counties: Humphreys, Jefferson, Montgomery, and Tallahatchie Counties.

According to the *FY 2005 State Health Plan*, there are four ESRD facilities located 26 to 34 miles from Montgomery County. The ESRD facilities are as follows: RCG Grenada, Grenada County (26 miles); RCG Eupora, Webster County (31 miles); RCG Greenwood, Leflore County (28 miles); and FMC Kosciusko, Attala County (34 miles).

Presently, there are 29 ESRD patients in Montgomery County, and 21 of these patients drive 25 miles to RCG facilities in Greenwood and Grenada. Secondly, the remaining eight patients drive to other RCGMI facilities located a great distance from Montgomery County. To address these concerns and ensure that the lives of ESRD patients are not compromised in any way, the applicant states that the proposed ESRD facility will eliminate the driving distance and offer accessibility to Winona patients so they will have longer dialysis treatments. If a CON is approved, the applicant estimates that 25 Winona County ESRD patients will be able to continue dialysis treatment at Renal Care Group-Montgomery County.

For the past 12 months, surrounding ESRD facilities had an annual utilization rate of less than 49.0 percent. The applicant would not be in compliance with this criteria based on the previous year Criteria and Standards listed in the *Plan*; however, the *FY 2005 State Health Plan Addendum*, adopted by the Mississippi Board of Health on July 14, 2004, waives the utilization criteria because there is not a facility in Montgomery County and its ESRD relative risk score is 1.5 or higher.

SHP Criterion 2 - Number of Stations

The applicant states that the ESRD facility will contain six hemodialysis stations in the county of Montgomery and in the city of Winona, Mississippi.

SHP Criterion 3 - Minimum Utilization

RCGMI, which manages Renal Care group facilities in the Grenada, Greenwood, and Lexington areas, currently dialyzes 21 patients who live in the Winona area. The applicant states that each patient dialyzes three (3) times per week or 13 times per month. However, due to illness and hospitalization, most patients dialyze at the facility twelve (12) times per month on average.

The chart below indicates how many procedures will be performed within the first three years after the RCG of Winona is approved for a CON.

Minimum Utilization			
	Year 1	Year 2	Year 3
Projected No. of Dialyses	4,032	4,320	4,464
Utilization Rate	72%	77%	79%
Number of dialysis is based on year end data. Utilization Rate is based on Optimum 75% utilization being defined as an average of 702 dialyses/station per year as per page XIII-28 of the <i>FY 2005 State Health Plan</i> .			

Briefly, the applicant states the *FY 2005 State Health Plan* reports that Montgomery County has a 2005 population projection of 12,381. The *Mississippi Population Projections for 2005, 2010, and 2015, March 2002*, book published by the Center for Policy Research and Planning shows that 5,799 non-whites and 6,582 Caucasians live in Montgomery County. The 2000 Census states that 45% of the non-white population is African-American (2,610).

Equally important, Medicare Certification records (maintained by the Mississippi State Department of Health, Division of Licensure and Certification), Health Care Financing and Administration (HCFC), and ESRD Network 8, Incorporated determine current or projected utilization of services. Based on 2003 data provided by ESRD Network 8, the applicant states that Mississippi had an ESRD incidence rate of 242.70 per million whites, 715.05 million per non-whites, and 425.54 for the state as a whole. In turn, the applicant calculated that RCG of Winona would provide ESRD services to 5.74 new patients per year, 1.6 new white patients and 4.15 non-white patients. In addition, the report indicates that Montgomery County had an incidence rate of 11 new patients based on 888.46 per million.

Since Network 8 used a higher Mississippi incidence rate of 888.46 million, the applicant feels Winona will likely experience a growth rate of 8 patients per year in Montgomery County. The applicant expects RCG of Winona to have 33 patients at the end of the first year, 35 patients at the end of the second year, and 31 at the end of the third year. As a result, RCG of Winona will be fully utilized and will maintain a sufficient utilization rate during the first three years of operation.

Currently, 10.9% of all RCGI patients participate in the home dialysis program based on the fact that 5.5% of their new patients choose home dialysis as their form of treatment. Consequently, the applicant anticipates that one patient will begin home dialysis during the first three years of operation.

The applicant indicates that the 2003 statewide mortality rate for RCGI was 19% and projects that five patients per year will expire. Also, RCG expects 1.5 percent of patients to undergo transplantation each year. The combination of the two rates will produce 31 patients by the end of the third year.

The proposed facility will be located in Montgomery County, which is from 26 to 34 miles from Attala, Grenada, LeFlore, and Webster County facilities. ESRD facilities in each of these counties experienced annual utilization rates less than 60 percent, far less than the required 80 percent annual utilization rate. However, the *Plan* waives the utilization rate based on a need for ESRD services in Montgomery County.

SHP Criterion 4 - Minimum Services

RCG affirms that the facility will provide extensive professional support from social workers and other such trained staff members.

SHP Criterion 5 - Access to Needed Services

RCG of Winona affirms that the applicant will provide reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients. The applicant provided a copy of a transfer agreement with the University of Mississippi Medical Center. In addition, RCG of Winona states that there will be access to inpatient routine and acute hemodialysis services through an agreement with Grenada Lake Medical Center or Greenwood Leflore Hospital. Once a CON has been approved, an agreement with a local health care facility will be entered for stabilization of patients pending transfer to hospitals capable of providing acute services.

SHP Criterion 6 - Hours of Operation

The RCG of Winona will open between the hours of 6:00 a.m. to 7:00 p.m. and will schedule three treatments per station. Patients who work each day and cannot dialyze between regular hours will be accommodated after hours.

SHP Criterion 7 - Home Training Program

Patients who obtain services for the first time at all RCG facilities in Mississippi will be counseled on the availability of the home-training program and the requirements to enter the home/self-dialysis program. No self/home training stations are being requested for this facility; however, 10.9% of RCG's existing patients are home patients. If patients are medically eligible and receptive to such a program, the applicant states that registered nurses employed by RCG will provide home-training to all patients.

SHP Criterion 8 - Indigent/Charity Care

The applicant affirms that RCG of Winona will provide a "reasonable amount" of indigent/charity care and serve approximately 0.68% indigent/charity care patients. The majority of all RCGI patients are Medicaid or Medicare recipients and do not require a great deal of unreimbursed care; however, the applicant assures that no patient is denied services due to an inability to pay.

SHP Criterion 9 - Facility Staffing

The applicant included a documented list of the proposed facility's staffing by category and the qualification guidelines (minimum education and experience requirements), specific duties, and full time equivalents. Therefore, the applicant affirms that 4.35 FTEs will be hired based on RCG of Winona's expected utilization rate.

SHP Criterion 10 - Staffing Qualifications

The applicant affirms that the staff of the facility will meet, at a minimum, all requirements and qualifications as stated in 42 CFR, Chapter IV, Subpart U.

SHP Criterion 11 - Staffing Time

When the unit is in operation, the applicant affirms that at least one (1) R.N. will be on duty and at least two (2) persons will be present for each dialysis shift, one of which will be an R.N. In addition, the applicant affirms that the medical director or a designated physician will be on site or on call at all times when the unit is in operation. When the ESRD facility is not in operation, the applicant affirms that the medical director or a designated physician and one R.N. will be on call. Also, the applicant affirms that a nephrologist will always be available to facilities within the RCGI system.

SHP Criterion 12 - Data Collection

The applicant affirms that RCG of Winona will record and maintain the required data and shall make it available to the Mississippi State Department of Health as required by the Department.

SHP Criterion 13 Staff Training

RCG of Winona affirms that the applicant will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

SHP Criterion 14 -Scope of Privileges

The applicant affirms that it will provide access to doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the governing body of the facility.

SHP Criterion 15 - Affiliation with a Renal Transplant Center

The applicant affirms that they will enter into an affiliation agreement with a transplant center within one (1) year after the facility is opened and operating. The applicant provides a copy of the transfer agreement with the University of Mississippi Medical Center.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2000 revisions*, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

GR Criterion 2 - Long Range Plan

The long range development plan of RCG of Winona is to operate a facility that provides hemodialysis to patients who must dialyze during scheduled times during the week and on an outpatient basis. Also, the applicant states the purpose of the facility is to provide research, training, and supplies to enable selected patients to undertake dialysis at home. RCG of Winona will continue to improve the quality of life for patients with chronic and acute care renal failure.

GR Criterion 3- Availability of Alternatives

Presently, the 21 patients who live in the Winona area are traveling less than 30 miles to use the services offered at the Renal Group facilities in Grenada, Greenwood, and Lexington. A CON would give patients the opportunity to use a facility in the Winona area, therefore, eliminating the traveling distance. The applicant states there are no other alternatives to provide health resources and cost containment.

GR Criterion 4 - Economic Viability

Three year operating projections reflect a first year net loss of \$19,031, a second year profit of \$47,899, and a third year profit of \$54,989. The proposal reflects a capital expenditure of \$154,085 which will be funded from working capital currently available from operations. The applicant states the projections reflect sufficient resources to fund capital expenditures, but if necessary, working capital may be provided by Renal Care Group, Inc. The applicant also states that the financial statements contained in the application indicates that RCG has the monetary means to provide the same.

The proposed charge of \$122.55 is the Medicare reimbursement rate set by the Centers for Medicare and Medicaid Services, and is the same for all facilities. The projected levels of utilization are consistent with those experienced by similar facilities in the service area and/or state.

GR Criterion 5 - Need for the Project

RCG Grenada, Grenada County; RCG Eupora, Webster County; RCG Greenwood, Leflore County; and FMC Kosciusko, Attala County are located 26 to 34 miles from Winona, Mississippi, Montgomery County. Presently, there are 29 ESRD patients in Montgomery County, and 21 of these patients drive 25 miles to RCG facilities in Greenwood and Grenada. Secondly, the remaining eight patients drive to other RCGMI facilities located a great distance from Montgomery County. If a CON is approved, the applicant states that the proposed ESRD facility will eliminate the driving distance and offer greater accessibility to patients so that they will have longer dialysis treatments. The applicant projects that 25 Winona County ESRD patients will have access to RCG of Winona, Mississippi, Montgomery County.

The applicant states that 36.3% of Mississippi's population and 45% of Montgomery County's population is African-American. Based on RCGI's statistics, 78.6% of RCGI's patient population is African-American. RCG of Winona anticipates serving a higher incidence rate of African Americans in Montgomery County. Also, the facility will serve approximately 0.68% indigent care patients. However, two facilities, RCG Grenada and RCG Greenwood are less than 30 highway miles of the proposed project and are not at an 80% utilization level. Again, the *Plan* waives the utilization rate based on a need for ESRD services in Montgomery County.

The application states that community officials recognize that RCG of Winona complies with all federal regulations regarding community service and supports the RCG's efforts to service all patients in Service Area 2 regardless of race, creed, sex, race, or ability to pay.

GR Criterion 6 - Access to the Facility or Service

All patients will be served without regard to race, sex, age, physical abilities, or ability to pay. Also, RCG of Winona will serve approximately 0.68% indigent care patients.

GR Criterion 7- Information Requirement

RCG of Winona affirms that they will record and maintain the information required by this criterion and shall make the data available to the Mississippi State Department of Health within fifteen (15) business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

RCG of Winona affirms that the proposed service will meet the needs of current RCGI patients. Since the majority of ESRD patients in Winona are currently being served by other RCGI facilities in the counties surrounding Montgomery County, there will be no significant adverse impact on existing providers of ESRD services.

GR Criterion 9 - Availability of Resources

The applicant states the required staff will include an Administrative Registered Nurse who will be named from within the existing nursing personnel in the RCG organization. RCG will recruit Registered Nurses and Licensed Practical Nurses from area colleges, universities, and local community colleges.

Also, Dialysis Technicians will be recruited from the local area. RCG will use Social Workers and Dietician services on a contractual basis. Dr. Randy White is the nephrologist who will serve as the medical director of RCG of Winona.

The applicant affirms that the facility shall provide access to all doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the governing body of the physicians. RCG operates 395 ESRD centers in 31 states. Also, RCG Mississippi, Incorporated operates 38 facilities in the state; thus, RCG has maintained a satisfactory staffing history at all facilities.

GR Criterion 10 - Relationship to Ancillary or Support Services

The applicant affirms there will be no adverse impact on any ancillary or support services.

GR Criterion 11 - Delivery of Health Services

The applicant states the establishment of RCG of Winona will enhance the training opportunities in the Winona area by allowing the facility to be open to required staff and students for the purpose of training, lectures, job opportunities, etc.

GR Criterion 12 - Access by Health Professional Schools

The transfer agreement included in the application indicates RCG of Winona, University Medical Center and local health personnel training programs have agreements with each other to share services by allowing health professional schools and the staff in the area to have access to the services for training purposes. Thus, all facilities are open for school tours, lectures, conferences, training and clinical placement opportunities for fellow residents and other allied health professionals.

GR Criterion 14- Construction Projects

The applicant states that they will enter a low-cost lease agreement with Tyler Holmes Memorial Hospital to relocate a modular building on the hospital's campus, as well as use their existing parking area to accommodate RCG of Winona ESRD patients. According to the applicant, the 1,920 square foot modular building is leased by RCGMI from General Electric and has been designed/converted into a facility to provide dialysis treatment services. Thus, there is no new construction and limited site work will be completed to the hospital site where the modular building will be positioned.

GR Criterion 15- Competing Applications

The Department received one application for ESRD services in Montgomery County, the north central portion of Mississippi. Therefore, there are no competing applications for this service.

GR Criterion 16 - Quality of Care

Currently, RCGMI operates 395 ESRD centers in 31 states and 38 facilities in Mississippi. The applicant assures that for 31 years RCGMI has demonstrated compliance with State and Federal licensure, accreditation, and certification standards and will continue to provide quality care to the residents of Mississippi.

IV. FINANCIAL FEASIBILITY

A. CAPITAL EXPENDITURE SUMMARY

A. CAPITAL EXPENDITURE SUMMARY	
Construction Cost -New	\$0.00
Construction Cost-Renovation	\$0.00
Capital Improvements, i.e. (minor painting and repairs, refurbishing)	\$0.00
Total Fixed Equipment Cost	\$0.00
Total Non-Fixed Equipment Cost	\$104,085.00
Land Cost	\$0.00
Site Preparation Cost	\$0.00
Fees (Architectural, Consultant, etc.)	\$25,000.00
Contingency Reserve	\$25,000.00
Capitalized Interest	\$0.00
Other Cost (Specify)	\$0.00
TOTAL PROPOSED CAPITAL EXPENDITURE	\$154,085.00

NOTE: There is no new construction associated with this project and limited site work will be completed to the hospital site where the modular building will be positioned.

B. Method of Financing

There is no debt associated with this proposal. The proposed project will be funded from working capital currently available from operations.

C. Effects on Operating Costs

The applicant projects the following expenses, utilization, and results from operation for the first three years of operation:

	First Year	Second Year	Third Year
Total Net Revenues	\$807,840	\$879,120	\$955,470
Operating Expenses:			
Salaries, Wages, and Benefits	266,830	221,180	240,390
Supplies and Misc. Expense	326,070	354,840	385,660
Interest Depreciation & Amortization	15,811	15,811	15,811
Bad Debt	24,240	26,370	28,660
Facility Rent	20,580	16,940	17,380
Other Expenses	173,340	165,670	177,450
Total Expenses	\$826,871	\$800,811	\$865,351
Income Before Income Taxes	(19,031)	78,309	90,119
Provision for Income Taxes	0	30,410	35,130
Net Income	\$-19,031	\$47,899	\$54,989
Total Treatments	4,032	4,320	4,464
Cost/Treatment	\$205.07	\$185.37	\$193.85
Charge/Treatment	\$200.37	\$203.50	\$214.04

D. Cost to Medicaid/Medicare

ESRD treatment is a Medicare entitlement. The Medicare reimbursed charge for the facility per dialysis is \$122.55, a rate set by the Centers for Medicare and Medicaid Services.

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application, and the Division of Health Planning and Resource Development received written comments from the Division stating that ESRD facility services will be paid based upon utilization once the facility is in operation. In addition, the Division of Medicaid states that cost to Medicaid cannot be determined at this time.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the establishment of an end stage renal disease facility/service as contained in the *2005 Mississippi State Health Plan*; Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2000*; and all adopted rules, procedures, and plans of the Mississippi State Department of Health. Specifically, there are two other facilities which are located less than 30 miles from the proposed facility. These facilities are RCG Grenada (26 miles) and RCG Greenwood (27 miles). For the past 12 months, both facilities had an annual utilization rate of 49.0 percent. The proposed facility will be located in Montgomery County, which is 26 to 38 miles from Attala, Webster, Grenada, and LeFlore County facilities. ESRD facilities in each of these counties experienced annual utilization rates less than 49.0 percent, far less than the optimum 75 percent annual utilization rate. However, the *Plan* waives the utilization rate based on a need for ESRD services in Montgomery County.

The Division of Health Planning and Resource Development recommends approval of this application submitted by Renal Care Group-Montgomery County, LLC for the establishment of a six-station ESRD facility in Winona, Mississippi.